

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of
SVETLANA A. SUKHISHVILI, et al.

Group Art Unit: 1618

Serial No. 10/624,993

Examiner: HUANG, Gigi
Georgiana

Confirmation No.: 8177

Filed: July 22, 2003

For: METHODS FOR CONTROLLED
RELEASE OF MOLECULES FROM
LAYERED POLYMER FILMS

I hereby certify that this correspondence is being electronically
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P.O. Box 1450
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ELECTION

Sir:

This Election is made in response to an Office Action mailed on August 27, 2007, in which a shortened statutory period of one month (i.e., until September 27, 2007) was set for response. The period for response to the Office Action has been reset to November 27, 2007 by the Petition submitted herewith.

As an initial matter, Applicants' attorney notes, with appreciation, that the Examiner allowed a telephonic interview with William Smith (Reg. No. 46,459) on October 25, 2007, regarding the election requirements discussed

herein. Unfortunately, no agreement was reached regarding the scope and burdens of such election requirements.

In the afore-mentioned Office Action, the Examiner requested an election under 35 U.S.C. § 121 between the following groups of claims:

Group I: Claims 1-6, drawn to a method for controlled release of molecules from a film, comprising a polymer, a first molecule, and a second molecule;

Group II: Claims 7-14, drawn to a method for the controlled release of molecules from a film, comprising a polymer, a molecule, a first solution at a first ionic strength, a second solution at a second ionic strength, a third solution at a third ionic strength, and a fourth solution at a fourth ionic strength; and

Group III: Claims 15-20, drawn to a method for controlled release of macromolecules from a film comprising a polymer and a macromolecule.

With respect to the above-stated election requirement, Applicants elect **Group III** (Claims 15-20), for further prosecution herein.

The Examiner required a further election from among the following **species**, as quoted from the Office Action:

- a. The methods of adjusting the pH of the film:
 - 1) to create a second excess charge opposite to the first excess charge and contacting the film with the macromolecule solution, *prior* to

adjusting the pH of the film to create the first excess charge to approximately one.

2) to follow in the following sequence: adjusting the pH of the film to create the first excess charge to approximately one *first, then* to create a second excess charge opposite to the first excess charge, and then contacting the film with the macromolecule solution, and repeating the sequence.

b. wherein the macromolecule is:

- 1) a polymer or
- 2) an oligomer or
- 3) a bioactive agent.

Before stating the election, Applicants' attorney wishes to note that neither species a.1 or a.2, as described in the Office Action, corresponds exactly to a claim in the application. These species would correspond to Claims 17 and 18, respectively, if the phrase "to approximately one" were eliminated from the descriptions. When the film is constructed, the charge balance (i.e., the ratio of positive charges to negative charges) is approximately one, as is stated in step (c) of Claim 15. However, pH variation will create an excess charge (i.e., a charge disbalance, with the number of ionized groups of one sign becoming greater than the number of ionized groups of opposite sign). Therefore, since the descriptions of species a.1 and a.2 address the creation of excess charge, rather than the construction of the film, Applicants attorney urges that the phrase "to approximately one" be deleted from the descriptions.

Trusting that the Examiner will favorably consider the aforementioned deletion, the Applicants elect **species a.2**, corresponding to Claim 18, for further prosecution herein. Applicants also elect **species b.3**, a bioactive agent, which species corresponds to Claim 20, for further prosecution herein.

In addition to the aforementioned election requirements, the Examiner required an election of **single specific species** from each of the following species, as quoted from the Office Action:

- a. the polymer forming the multilayer film.
- b. wherein the macromolecule is:
 - 1) a polymer or
 - 2) an oligomer or
 - 3) a bioactive agent.

With respect to **a.**, Applicants' elect the single specific species **polymethacrylic acid (PMAA)** as the polymer forming the film. With respect to **b.**, Applicants elect **lysozyme (Lys)**, a bioactive agent, as the single specific species of macromolecule to be further prosecuted herein.

Applicants hereby reserve their right to file one or more divisional applications directed to the non-elected groups, species or single specific species disclosed in the application.

In view of the foregoing elections, Applicants' and their attorney respectfully request that the present application be examined on its merits. Should there remain any questions or other matters whose resolution could be

advanced by a telephone call, the Examiner is invited to contact the undersigned attorney at his number below.

The Examiner is authorized to charge a fee of \$230 to Deposit Account 501561 for the accompanying Petition to extend the period for response by two months. Applicants' attorney believes that no other fees are due for this Amendment or the Petition. If any such fees are due, including any petition fees or fees for extending the time for response, the Examiner is authorized to charge any deficiency, and/or credit any overpayment to Deposit Account No. 501561.

Respectfully submitted,

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